510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

APR 0 5 2013

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the SIDEKICK® EZ FRAME™ External Fixation System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 5677 Airline Road Arlington, TN 38002
Date:	January 4, 2013
Contact Person:	Ryan Bormann Regulatory Affairs Specialist II (901) 867-4409
(a)(2). Proprietary Name:	SIDEKICK® EZ FRAME™ External Fixation System
Common Name:	External Fixation Device
Classification Name and Reference:	21 CFR 888.3030 – Class II
Device Product Code, Device Panel:	KTT, Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
(a)(3). Predicate Device:	K043289 E-Z FRAME EXTERNAL SURGICAL SUPPORT BOOT

(a)(4). Device Description

The SIDEKICK® EZ FRAME™ External Fixation System uses a series of pins and wires for compression or distraction in the foot and uses a boot to secure the tibia. The system is adjustable to accommodate variations in patient anatomy. The SIDEKICK® EZ FRAME™ External Fixation System is compatible with the SIDEKICK® FREEDOM External Fixation System (K043289) components, and these components provide additional fixation options in the system.

(a)(5). INTENDED USE

- Triple arthrodesis
- Isolated rearfoot arthrodesis
- Midfoot arthrodesis
- Comminuted trauma
- Diabetic Charcot reconstruction
- Most foot pathology not requiring fixation above the ankle

(a)(6). Technological Characteristics Comparison

The subject device operates in the same method as the predicate.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Through mechanical component analysis and comparison the subject system does not represent a new worst-case.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject device system can be expected to perform at least as well as the predicate systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Wright Medical Technology, Inc.
% Mr. Ryan Bormann
Regulatory Affairs Specialist II
5677 Airline Road
Arlington, Tennessee 38002

Letter dated: April 5, 2013

Re: K130044
Trade/Device Name: SIDEKICK® EZ FRAME™ External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: KTT, HTY, JEC
Dated: January 4, 2013
Received: January 8, 2013

Dear Mr. Bormann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130044

Device Name: SIDEKICK® EZ FRAME™ External Fixation System

Indications For Use:

- Triple arthrodesis
- Isolated rearfoot arthrodesis
- Midfoot arthrodesis
- Comminuted trauma
- Diabetic Charcot reconstruction
- Most foot pathology not requiring fixation above the ankle

Prescription Use __xxx__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)
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